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Manitoba

REPORT AND RECOMMENDATIONS OF THE WORKING GROUP ON BREAST CANCER SCREENING

TO THE

MINISTER OF HEALTH

DECEMBER, 1991

REPORT AND RECOMMENDATIONS OF THE BREAST CANCER SCREENING WORKING GROUP

EXECUTIVE SUMMARY

Based on a detailed examination of the research data, along with the experience of existing programs and expert opinion, the Breast Cancer Screening Working Group has not found convincing evidence to support implementation of a breast cancer screening program at this time.

Despite earlier optimism about the benefits of mammography screening, a more conservative approach to breast cancer screening is now being considered both nationally and internationally, pending clear evidence of benefit mass mammography screening.

The recommendations of the Breast Cancer Screening Working Group at this time are outlined below.

1. **That no mammography screening program be initiated in the province at this time.**

   Rationale: The scientific evidence to date provides insufficient proof of health benefit to justify implementation of a provincial mammography screening program at this time.

2. **That screening mammography be discouraged in asymptomatic women under the age of 50 years.**

   Rationale: Research literature indicates that mammography screening provides no benefit in terms of mortality reduction from breast cancer in women under the age of 50 years.

3. **That the provincial government support the development and implementation of an information program for health professionals. This program will be developed in collaboration with relevant professional groups and associations.**

   Rationale: Studies show that women are strongly influenced by their physician's recommendations regarding breast cancer screening. Sound policy for mammography screening requires the understanding and cooperation of an informed health care community.

4. **That a system be developed to provide women throughout the province with current information about breast cancer screening. An initial and interim measure will be the development and distribution of an information resource which focuses on the current knowledge and assists women in decision-making about mammography in**

conjunction with their health care providers.

Rationale: Promotional media campaigns which encourage mammography screening provide women with an unbalanced view of the benefits of mammography. Government directed public education, and media campaigns, are required to increase awareness of the most recent evidence about mammography screening.

5. **That the Government of Manitoba promote appropriate research for breast cancer including breast cancer screening.**

Rationale: Many questions bearing on breast cancer and breast cancer screening still remain to be answered.

6. **That a Breast Cancer Screening Advisory Group be established, with appropriate membership, to monitor evidence regarding breast cancer screening including results of the Canadian National Breast Screening Study. Reassessment of recommendations and economic implications for a breast cancer screening program for Manitoba women should be ongoing.**

Rationale: Recently, new information about breast cancer screening from the Canadian National Breast Screening Study questions the benefit of presently established mammography screening programs. The final results from the Canadian National Breast Screening Study, the meta analysis being conducted by Cambridge Conference on Breast Cancer Screening and the review conducted by the Canadian Coordinating Office for Health Technology Assessment will influence planning in Manitoba. Until these results are available for review, the ongoing monitoring of new evidence and mammography screening programs in other provinces and countries should continue.

Breast cancer is the leading cause of cancer death in women. In Canada one in every ten women will develop breast cancer during her lifetime and this incidence appears to be rising although the death rate is stable. In Manitoba 198 women died from breast cancer during 1991 and 590 new cases were diagnosed.

The cause(s) of breast cancer are not known and risk factors which have been associated with the disease such as family history, high fat diet and late childbearing can only be identified in 25% of diagnosed cases. Age, on the other hand, appears to be a highly significant factor in breast cancer. The risk increases with age and the progression and outcome appear to differ between pre and post menopausal women. Research initiatives are being actively pursued to determine the causes and to find better treatment methods for the disease.

As with other types of cancer, early detection has been perceived as a strategy to improve outcome. Three methods of early detection for cancer of the breast are currently employed; breast self examination, professional breast examination, and mammography. The dilemma regarding breast cancer screening is in determining: i) the degree of benefit to women from these screening modalities and ii) the cost/ effectiveness of a population based breast cancer mammography screening program.

The Working Group's conclusions and recommendations are based on analysis of the existing data. It takes into account the fact that research and evaluation in this area are ongoing and will be providing new information which may alter existing decisions and directions.

A number of international trials and studies have been undertaken to determine the effectiveness of screening asymptomatic women for breast cancer. Overall, analysis of the six major studies indicates that under controlled conditions and with a 70% compliance rate, for women aged 50-69, a 30% mortality reduction has been achieved. No mortality reduction has been demonstrated by this data for women under 50 years of age.

Approximately 20,000 mammograms were performed in Manitoba in 1989/90. It is estimated that, of these, 60% (12,000 mammograms) were performed on asymptomatic women for screening purposes; and, that 4,400 of these were performed on women aged 40-49 years, the age group with no established benefit. The cost of mammograms performed on asymptomatic women was $950,000.

Preliminary cost estimates reveal that the cost of establishing a mammography screening program in Manitoba would be approximately four million dollars, with ongoing yearly costs projected at approximately 2.5 million dollars. A major portion of both these amounts would be add on costs to the system.

These are considered conservative estimates and are based on a 70% compliance. They do not include any of the additional expenditures generated by screening.

In order to ensure the appropriate future of mammography screening, the Working Group has determined that on-going monitoring of research data by an Advisory Group will be necessary. At the same time, an educational campaign for the public and health professionals should be developed to provide balanced information about the risks, benefits and limitations of mammography and to report on the Working Group's conclusions. These education strategies would have an estimated cost of $20,000.

INDEX

EXECUTIVE SUMMARY

INDEX 1

BREAST CANCER SCREENING WORKING GROUP MEMBERSHIP AND PROCESS 3

GLOSSARY 6

1. INTRODUCTION

1.1 Breast Cancer: An Overview 8

1.2 Principles of Screening 12

1.3 Breast Cancer Screening 13

2. PRESENT MAMMOGRAPHY ACTIVITY AND COSTS IN MANITOBA 15

3. MAMMOGRAPHY SCREENING: THE EVIDENCE

3.1 Major Mammography Screening Trials 20

3.2 Evaluation of the Evidence 23

3.3 Implications for women aged 50 - 69 years 25

3.3 Implications for women aged 40 - 49 years 27

4. APPROACHES IN OTHER JURISDICTIONS

4.1 National 28

4.2 International 30

5. THE MAMMOGRAPHY SCREENING DILEMMA 32

6. CONCLUSIONS 36

7. RECOMMENDATIONS 37

7. CONCLUDING SUMMARY 46

8. BIBLIOGRAPHY 47

TABLES

1A. Incidence and Mortality Figures for Breast Cancer in Manitoba Women:- 1986-1990. 8

1B. Incidence and Mortality Figures for Breast Cancer in Manitoba Women by Age Group: 1990. 9

2. Estimated age - Standardized Incidence Rates for Breast Cancer per 100,000 Female Population: 1991. 10

3. Number and cost of bilateral mammograms performed on women of all ages at private x-ray facilities from 1980/81 to 1989/90 and projected to 1991/92. 17

4. The Estimated Number and Cost of Mammograms performed in Manitoba on Women Aged 40 years and Older: 1989/1990. 18

5. Summary of Major Mammography Screening Studies. 20

6. Canadian Provinces with Mammography Screening Programs. 28

BREAST CANCER SCREENING WORKING GROUP

MEMBERSHIP AND PROCESS

The Breast Cancer Screening Working Group was convened in January, 1991, on the direction of the Deputy Minister of Health, with the Women's Health Directorate taking the lead coordinating role on behalf of government. The group's mandate was to:

1. Provide a preliminary cost analysis of options for breast cancer screening in Manitoba by April 1991.

and

2. Prepare a final report on the advisability of a breast cancer screening program for Manitoba women, outlining detailed recommendations, including economic implications and implementation strategies.

Group membership was by invitation to ensure representation from relevant professional organizations, women, and other key stakeholders in the issue.

The Working Group met over a period of 11 months, to assess and analyze current and ongoing research literature on breast cancer screening and to share other appropriate sources of information and opinion. Numerous reports and papers were considered including those listed in the attached bibliography. As part of the process, consultations were held with a number of individuals with

knowledge and expertise in breast cancer screening. The following list includes the names and affiliations of the members of the Working Group.

WORKING GROUP MEMBERS

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GLOSSARY

An understanding of the terminology related to breast cancer screening is necessary for a complete understanding of this report. The following list contains the principle terms and their definitions as utilized by the Working Group for the purpose of this report.

Benign Breast Condition - breast tissue that has a non malignant abnormality.

Biopsy - removal of a piece of tissue for laboratory examination by a pathologist to determine what disease process is present.

Breast Cancer - a malignancy in the breast. A difference in tumor biology exists between pre and post menopausal women.

Breast Self Examination - the regular examination (monthly) of the breast by the woman herself.

Diagnostic Mammography - a radiologic examination utilized to evaluate a patient who has symptom(s) (ie. a breast lump or other abnormality).

Early Detection - the discovery of cancer at the earliest possible stage before symptoms would become apparent to a woman.

Mammography - X-ray examination of the breast.

Professional Breast Examination - the physical examination of the breasts by trained medical or nursing personnel. When performed during a periodic health examination by a skilled health professional, it may be an important method for detecting early breast cancer.

Screening Mammography - a simplified x-ray examination utilized to detect unsuspected breast cancer at an early stage in a large number of asymptomatic women. It differs from diagnostic mammography in that it is performed on healthy women with no symptoms of breast abnormality.

INTRODUCTION

Breast Cancer: An Overview

In spite of progress in cancer research, and in methods of detection and treatment, the death rate from breast cancer has remained fairly constant. Women continue to die from breast cancer in 1991 at the same rate as in 1970.

Increases in the incidence rate (or number of new cases) of breast cancer in women are causes of major concern in most Western nations. It is not clear to what extent the increase in incidence is due to improved diagnostic techniques and data collection or to actual increase in the disease. Tables 1A and 1B contain recent incidence and mortality figures for breast cancer in Manitoba.

Table 1A Breast Cancer in Women: Incidence & Mortality Figures for Manitoba, 1986-1990

Year	New Cases	Deaths
1986	575	216
1987	544	178
1988	645	184
1989	655	157
1990	650	198
1991	590	230

Source: Manitoba Cancer Treatment and Research Foundation

Table 1B Incidence and Mortality Figures for Breast Cancer in Manitoba Women by Age Group, 1990

Age Group	New Cases	Deaths
Under 40	41	6
40 - 49	94	20
50 - 59	130	33
60 - 69	157	46
70 and over	228	93
TOTAL	**650**	**198**

Source: Manitoba Cancer Treatment and Research Foundation (1991 breakdown not available at time of writing)

The incidence of breast cancer varies from country to country. Currently in Canada, one in every ten women can expect to develop breast cancer sometime in her life. In the United States one in nine women will develop breast cancer. Rates are highest for the United Kingdom (England & Wales) and the Netherlands while the rate of breast cancer in Japan is among the lowest in the world, being one quarter that of the United Kingdom rate. Researchers have not been able to explain these variations, but suggest that an interaction between genetic and environmental factors, particularly diet, may be responsible.

There are variations in breast cancer rates between the Canadian Provinces (see Table 2). The incidence rate in Manitoba is one of the highest, although the mortality rate is similar to that in other provinces. These differences may reflect actual differences in the risk of breast cancer,

but they may also be affected by variation in provincial data collection methods.

Table 2. Estimated Age - Standardized Incidence Rates for Breast Cancer per 100,000 Population: Females,1991.

Canada	72
Newfoundland	54
Prince Edward Island	61
Nova Scotia	69
New Brunswick	64
Quebec	73
Ontario	72
MANITOBA	**78**
Saskatchewan	74
Alberta	72
British Columbia	79

Source: National Cancer Institute of Canada
Canadian Cancer Statistics 1991

Except for skin cancer, cancer of the breast is the commonest form of cancer for Canadian women and continues as the leading cause of cancer related death in spite of increasing rates of lung cancer among women. The risk of developing breast cancer increases with age; the older the woman, the greater her chances of developing breast cancer. A diagnosis of breast cancer in a primary relative, such as a mother or sister, also appears to increase risk. However, a family history of breast cancer or the presence of factors such as a high fat diet or late childbearing can be identified in only 25% of diagnosed cases of breast cancer.

For the individual woman breast cancer creates feelings of dread and anxiety. This fear and dread is probably related to its frequency and its apparent random occurrence.

psychological threat of breast cancer is also particularly strong; it is associated with a fear of both disfiguring surgery and the side effects from radiation or chemotherapy, and the expectation of death.

In the absence of preventive measures or a cure, attention has been directed towards techniques for the early detection of breast cancer. The theory being that, if a tumor can be identified before it has metastasized or spread to other parts of the body, it can be treated more successfully, with a resulting decline in mortality and morbidity. Determining the degree of benefit from early detection is an important research question. Determining the advantages of instituting periodic screening of asymptomatic women with mammography and/or physical examination of the breast has become an important public health question.

Integral to this issue is the influence of health education and public promotion campaigns on the utilization of mammography services by women. Appropriate and effective use of mammography will depend not only on the results of scientific research but also on the education of health professionals and the public about the benefits, risks and limitations of mammography screening.

Principles of Screening

Screening is defined as the periodic examination of a healthy population (ie. one that has no symptoms of abnormality). The purpose of a screening procedure is to separate those who probably have the disease from those who probably do not. The main objective is to reduce morbidity and mortality by facilitating both detection and early initiation of effective intervention.

Three characteristics must be present for a disease to be suitable for a screening program:

1. the disease should have serious consequences, and be recognized as such by members of the target population;
2. the disease must have a treatment that, when applied at the screen detected stage of the disease, is more effective than treatment applied after symptoms have led to diagnosis; and
3. the preclinical phase of the disease should have a high prevalence among the persons screened.

The ideal screening test should be highly accurate in identifying either the presence of the disease (high sensitivity) and its absence (high specificity). In addition to being both valid and reliable, a test must be acceptable to the population and cause minimal disturbance to the individual in its performance. Lastly, the screening test should be reasonable in cost.

Breast Cancer Screening

Breast cancer appears to meet some of the criteria for a screening program. The incidence and mortality rates are high; and the early detection and treatment of breast cancer appears to reduce morbidity and mortality. Currently three modalities are used individually or in combination for the early detection of breast cancer; breast self examination, professional or clinical breast examination, and mammography. Evidence that breast self examination reduces mortality is weak, but this activity is still encouraged, partly because most palpable breast cancers are discovered by women themselves. Relative to the other two modalities, breast self examination has the advantage of low cost and of being the only form of screening available for women who do not have access to professional breast examination or mammography. Professional breast examination, when performed by a skilled health professional, is better than self examination. One of the main objectives of the Canadian National Breast Screening Study is to evaluate the effectiveness of professional breast examination relative to mammography.

An effective mammography screening program requires costly and technologically sophisticated, dedicated equipment, technical quality control, professional quality assurance and patient follow-up. The involvement of a large number of women (70% compliance of designated women) must be ensured if a mammography program is to be cost effective.

Ensuring high level of compliance requires understanding by the public and by the enrolled women of the need for a maximum of two decades of participation in the screening program with possible sequential mammography and biopsies for the early detection of tumors. It is readily apparent that the costs of screening are higher with mammography than with breast self examination or clinical examination.

PRESENT MAMMOGRAPHY ACTIVITY AND COSTS IN MANITOBA

The following estimates provide an overview of current costs to the health care system incurred by breast cancer treatment and detection. It should be noted that figures for mammography services reflect only those bilateral mammograms provided in private x-ray facilities. Mammograms performed in hospitals are excluded from these calculations for two reasons: 1. mammography service data is not routinely collected by the hospitals; and
2. mammograms performed in hospitals are assumed to be mainly for diagnostic purposes. It is estimated that approximately 15,000 mammograms were performed in Manitoba hospitals in 1989.

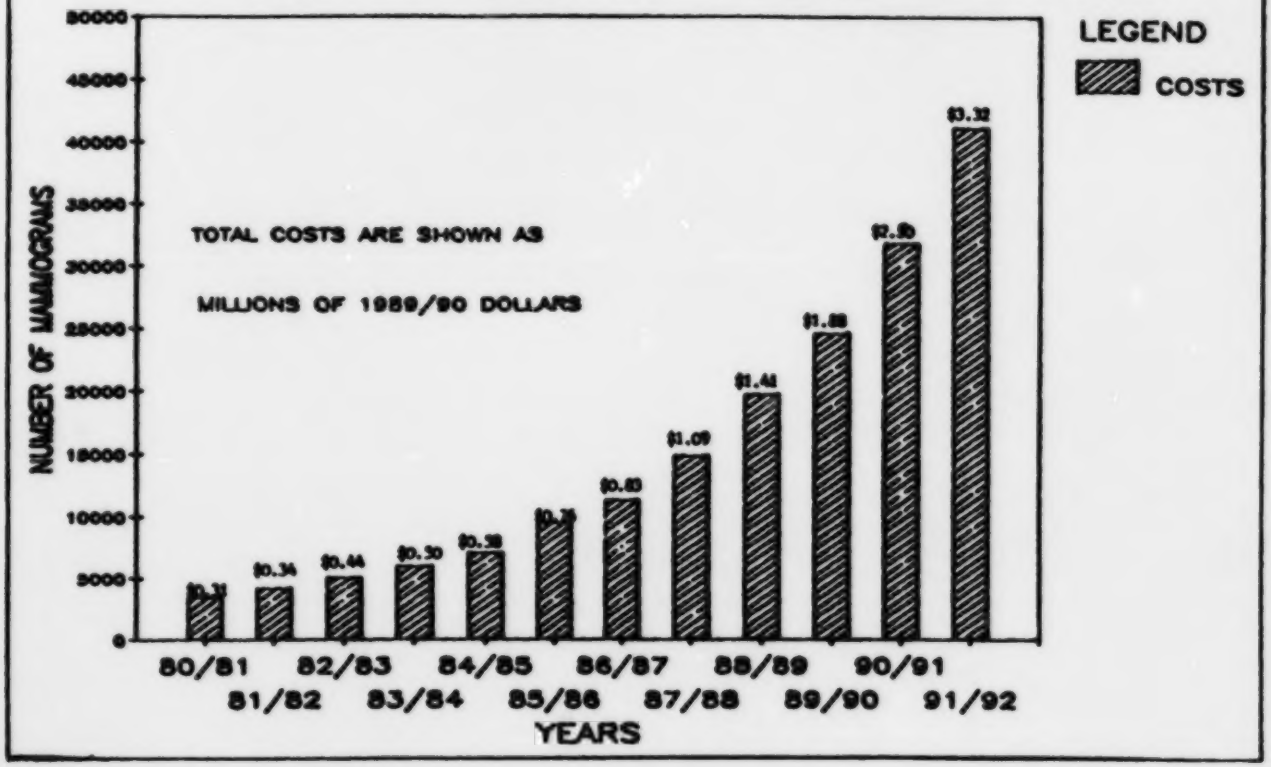
The Manitoba Cancer Treatment and Research Foundation Annual Report recorded 198 breast cancer deaths in women in 1990. Using an average life expectancy of 80 years for Manitoba women, this represents a loss to the community of approximately 2,615 life years. The cost to the health care system of treating one woman with breast cancer from the time of detection to the time of death has been estimated at $50,000. The physical, psychological, social, personal and economic costs of breast cancer to a women and her family are more difficult to estimate.

Screening may increase the management costs of breast cancer, particularly if the only result of early detection is to prolong treatment, follow-up, and terminal care, without significantly extending life expectancy. Yet, in

the absence of prevention, early detection programs are seen by some as the best way to deal with breast cancer and mammography screening, is being promoted as the modality of choice. Change in demand for mammography in Manitoba is reflected in Manitoba Health Services Commission data which show an overall increase in services rendered, for women of all ages, from approximately 6,000 mammograms (private clinics) in fiscal year 1983/84 to 24,590 mammograms in 1989/90 (a 310% increase). This data represents all bilateral mammography with no distinction between mammography for diagnostic or screening purposes. The increase in the number of bilateral mammograms performed in private x-ray facilities and the escalation in costs from 1980/81 are shown in Table 3. (Figures for 1990/91 and 1991/92 are projections).

In 1989, 20,409 bilateral mammograms, at a cost of $1.6 million were performed on women aged 40 and above (4181 mammograms were for younger women). This represents an average annual rate of increase in mammography service of 29.4% over the previous two years and a cost increase of 33%. Using this information to project the total number of services for 1991/92, the total number of bilateral mammograms for women 40 years and above will be 34,173 at an estimated cost of $2.7 million.

TABLE 3
NUMBER AND COSTS OF BILATERAL MAMMOGRAMS
PERFORMED AT PRIVATE X-RAY FACILITIES
FROM 1980/81 TO 1989/90 AND PROJECTED TO 1991/92



Bilateral mammograms may be performed for diagnostic reasons, but Manitoba radiologists and technicians suggest that approximately 60% of the 20,409 bilateral mammograms in 1989 were done on asymptomatic women for screening purposes. Thus, 12,246 mammograms were performed at a cost of $950,000 on asymptomatic women of whom 37% (4,442) were aged 40 to 49. (See Table 4)

TABLE 4:
The estimated number and costs of mammograms performed in Manitoba on asymptomatic women aged 40 years and older in 1989/90.

AGE GROUPS	40-49	50-69 Target group	70+	TOTAL
Total number of mammograms	7,548	10,603	2,258	20,409
Estimated number of mammography services for asymptomatic women[1]	4,529	6,362	1,355	12,246
Estimated cost of mammography for asymptomatic women[2]	350,000	490,000	105,000	950,000
Estimated number of asymptomatic women who had mammography[3]	4,442	6,223	1,337	12,002
Population of women in each age group in Manitoba	67,528	98,127	59,018	224,673

Note:

- Figures in this table do not include mammograms performed in hospital facilities which include some asymptomatic women.

Assumptions:

[1] based on the assumption that 60% of mammograms performed on women 40 years and older are for screening purposes.

[2] based on the assumption that 60% of mammography costs were related to provision of services for asymptomatic women.

[3] based on the assumption that 60% of women aged 40 and above who have mammograms are asymptomatic.

Formalizing mammography screening services by establishing a population based program has been projected to have an approximate four million dollar start up cost with ongoing yearly expenditures of approximately $2.5 million. A major portion of these amounts would be add on costs to the system. These are considered conservative estimates and are based on a 70% compliance. They do not include any additional expenditures generated by screening. A decision not to implement such a program is expected to result in continued ad hoc utilization of diagnostic facilities for screening purposes. Currently, provincial mammography services for asymptomatic women costs $950,000/year (1989/90 estimation) and the numbers and expenditures are expected to continue to escalate given the current trends.

MAMMOGRAPHY SCREENING: THE EVIDENCE

Major Mammography Screening Trials

Four randomized clinical trials and two case control studies provide the bulk of the current epidemiological evidence on the effect of mammography screening on breast cancer mortality. A fifth trial, the Canadian National Breast Screening Study, is expected to publish its final results in early 1992. The results of these previous studies suggest that mammography screening reduces mortality in women 50 years and older, although the degree of benefit varies from one study to another. (See Table 5)

TABLE 5
Summary of Major Breast Cancer Screening Studies

Screening Study	Number of Women	Eligible Age At Entry	Results for Women 40-49	Results for Women 50+
HIP[5] 1963-1967 New York	62,000	40-64	Statistically insignificant reduction in breast cancer mortality after 18 years.	A reduction in breast cancer mortality of 40% after nine years of follow-up
DOM[4] 1974- Netherlands	23,511	50-64	Not Included	A reduction in breast cancer mortality of 70%
NIJMEGEN[4] 1975- Netherlands	30,000	35+	No reduction in mortality	A reduction in breas cancer mortality of 52%
UK TRIAL[11] 1981-	240,000	45-65	After seven years breast cancer mortality reduced 20% in women offered screening. Results not yet reported by age group.	
TWO COUNTRY STUDY[2] 1977 Sweden	162,981	40+	No reduction in breast cancer mortality	A reduction in breast cancer mortality of 40 %after seven years of follow-up.
MALMO[11] 1977 Sweden	42,000	45-69	More deaths after breast cancer in group offered screening than control group.	A reduction in breast cancer mortality of20% after 12 years of follow-up.
NBSS[7] 1980-1988 Canada	90,000	40-59	Preliminary results reveal after seven years no early reduction in breast cancer mortality in women 40-49 years. Final complete report pending.	

Although some benefit from mammography screening has been demonstrated only in women aged 50 and above; none of these studies have reported a statistically significant reduction in mortality for women younger than 50 years at entry into a study.

The Canadian National Breast Screening Study, started in 1980 and completed its screening trial in early 1988. Approximately 90,000 women from two age groups (40 - 49, and 50 - 59 years) were recruited in six Canadian provinces, including Manitoba. The primary research objectives were:

1. To determine whether annual screening by mammography and physical examination reduces mortality from breast cancer in women 40 to 49 years;
2. To determine the contribution of mammography over and above physical examination in reducing breast cancer mortality in women aged 50 to 59 years.

Secondary objectives include:

- An assessment of whether an appropriate combination of risk factors for breast cancer can be derived to permit restricted screening to those at highest risk of the disease.
- The collection of data on the natural history of breast cancer so as to evaluate the optimum age at which screening should be commenced and its subsequent periodicity at different ages.

The Canadian National Breast Screening Study is the largest study undertaken to date to evaluate combination screening in women 40 to 49 years. Furthermore, it is the only study to evaluate the effect of mammography over and above physical examination in women 50 to 59. Although no mortality results are officially available from the Canadian National Breast Screening Study, Dr. Miller, Director of the Canadian National Breast Screening Study, reports that preliminary results show no benefit from mammography screening in women 40 - 49 years of age in the study data.

The lack of benefit for women 40 to 49 years, reported in the Canadian National Breast Screening Study, is consistent with other studies. Also, women in the 40 to 49 age bracket at entry into the Swedish Two County trial as well as women below 55 years of age in the Malmo trial initially reported more deaths from breast cancer in the groups offered screening than in the control groups.

While there are criticisms of the Canadian National Breast Screening Study, it is considered important because of its size and its use of randomization, and because it is much closer in many of its attributes to the conditions under which a provincial screening study would operate. If the final results confirm no benefit for women aged 40 - 49 and limited benefit for women 50 - 59, then the implications for setting up a provincial mammography screening program require very careful evaluation.

Evaluation of the Evidence

The more recent research and current literature on breast cancer screening reveals considerable controversy regarding the benefits of mammography, partly due to the methodological problems inherent in most research designs. Comparison of the results of the major breast cancer screening studies and trials is difficult because of diversity in setting, attendance, recruitment, study design and number of women years of follow-up.

Studies which examine screening for any cancer must answer two fundamental questions. First, does the screening modality permit earlier diagnosis? The premise of all the mammography screening trials is that mammography can detect some breast cancers before they are apparent by breast physical examination and, thereby, reduce mortality from this disease. The second and more important question, however, is whether the earlier diagnosis leads to a longer and more comfortable life for the individual woman.

The answer to this question remains inconclusive, owing to such factors as the interference of the following research biases: lead time, length bias, selection and over diagnosis bias. Lead time refers to the amount of time the point of diagnosis has been advanced by the application of a screening test. The survival rate (the time elapsing between diagnosis and death) may be lengthened without changing the length of life. Length bias is a problem

arising because of the growth rate of breast tumors. Fast growing tumors may develop and progress rapidly in the intervals between screening. Screening is more likely to detect slow growing cancers that are not sufficiently aggressive to reveal themselves clinically but will be found through mammography. These cancers have a better prognosis than the fast, progressive cancers. Therefore, survival rates among women having mammography will be a reflection of the type of cancer (more slow growing, less aggressive) likely to be detected by mammography.

Selection bias means that women who volunteer for screening are not representative of the general population. They may be more health conscious and perhaps thereby have a better prognosis than women who do not accept screening, but who develop breast cancer and come late to treatment. On the other hand, women who volunteer for screening are often more likely to know that they are at risk for breast cancer. Overdiagnosis refers to two separate processes: the misclassification of benign lesions as malignant, and the identification of lesions, either invasive or non invasive, which would not advance to become clinically manifest in a women's lifetime. These women undergo procedures for the diagnosis and treatment of lesions that would never prove life threatening and would not normally present for treatment. Inclusion of these women make the survival statistics look promising when, in fact, actual benefit may be questionable.

It is very difficult to eliminate these biases in even the most carefully controlled research design. Many people remain convinced that the results of the six studies shown in Table 5 have provided sufficient rationale for the development of mammography screening programs. Newer evidence from the Canadian National Breast Screening Study and the critical re-examination of the design problems in the earlier studies have led others to question this conclusion. The key questions still remain:
Is there any benefit from mammography screening to women 40 - 49 years? What is the degree of benefit for women 50 - 69 years? Why do higher mortality rates from breast cancer appear in women age 40-49 years, who receive mammography? And lastly, should mammography screening programs be implemented at this time, given the existing evidence?

Implications for Women 50 to 69 Years

The most important risk for breast cancer is age. There is evidence to suggest that women aged 50 years and older are likely to benefit by a reduction of breast cancer mortality from a mammography screening program. However, recent new evidence is questioning the extent of this benefit. Counterbalancing the possible reduction in mortality, a screening program would result in unnecessary anxiety and discomfort for several thousand women. In Manitoba, there are 98,127 women between the ages of 50 - 69 years. If the screening interval is every two years, as

recommended at the 1988 Federal-Provincial Health Ministers Conference, then 49,064 women would require screening yearly. Based on results of previous trials we can predict that with (an estimated 70% participation), approximately 2061 women per year would have initial false positive screening results (a 6% false positive rate). These would inevitably require physician consultation, diagnostic mammography and possibly biopsy. In the United States positive biopsy rates are as low as 10%, while in highly controlled European settings the rate of biopsy is much lower with positive rates of 60% for similar clinical groups.

To achieve the degree of benefit demonstrated by the screening trials requires the adherence to strict methods and quality of service equal to a research center. An enormous diversion of resources would be necessary to implement an effective province wide mammography screening program. Screening results in financial costs not only through the costs of the screening program itself, but also through follow-up investigations for women who have positive or suspicious screening exams. Screening of many thousands of women per year will divert resources and funds from other activities that might possibly yield greater benefits to womens health.

Implications for Women 40 to 49 Years

The available data suggests that there is no short term benefit - in terms of mortality reduction - when screening women 40 to 49 years. Only the Health Insurance Plan of New York (HIP) study, though not designed to evaluate the effect of screening by age, has shown any suggestion of effectiveness in this age group, and only after 18 years. However, a number of studies have demonstrated increased breast cancer mortality in women 40 to 49 during the first years of follow-up. The Malmo study recorded an excess mortality from breast cancer in women aged 45 - 55, and similar findings were reported in the Swedish Two County trial. The Canadian National Breast Screening Study, the largest trial in this age group to date, has provided preliminary data which show no grounds for optimism that an early beneficial effect of screening will be demonstrated.

APPROACHES IN OTHER JURISDICTIONS

NATIONAL

In Canada, breast cancer screening was the subject of a special workshop at the 1988 Federal-Provincial Health Ministers Conference. The principle recommendation emerging from the workshop was that "Canadian women between the ages of 50 - 69 years be offered a program of biennial screening by mammography and physical examination to take place in specialized centers". Screening was not recommended for women aged 40 - 49, due to inconclusive evidence of benefit for women in this age group. As a follow-up to the 1988 National Workshop, Health and Welfare Canada has organized ongoing cross jurisdictional meetings to facilitate the exchange of information and improve collaboration between the provinces for the development of breast cancer screening programs. Manitoba has participated in these meetings.

Breast cancer mammography screening programs are presently operational in the following five provinces and one territory:

TABLE 6.

PROVINCE	AGE BRACKET OF WOMEN RECRUITED	IMPLEMENTATION DATE OF SCREENING PROGRAM
Nova Scotia	50-69	June, 1991
Ontario	50-64	Fall, 1990
Saskatchewan	50-69	April, 1990
Alberta	50-69	Fall, 1990
British Columbia	40+ - No Upper Age Limit	July, 1988
Yukon	50+	December, 1990

Due to the early phase of mammography screening in Canada, the provinces that have undertaken mammography screening programs are as yet unable to provide evaluation regarding outcomes of mass screening.

Meanwhile, other provinces have taken a different approach to the issue of mammography screening. The Government of Quebec commissioned the Conseil d'Evaluation des Technologies de la Sante to undertake an evaluation of the evidence regarding the health effects as well as an estimate of costs of screening for breast cancer. The report published in November 1990, recommended improving the efficiency and effectiveness of current mammography practice. In addition, it recommended a delay in the launching of a formal mammography screening program until the final results of the Canadian National Breast Screening Study become available for review. The remaining provinces, Newfoundland, Prince Edward Island and the North West Territories, do not presently envision an organized screening program.

In May 1991, the Canadian Coordinating Office for Health Technology Assessment undertook a review of Canadian and foreign studies on breast screening focusing on: incidence of breast cancer, mortality, survival rates, risk benefit and cost effectiveness. The results of this review will be available in early 1992.

INTERNATIONAL

Mammography screening has been evaluated in several countries and screening programs have recently been implemented in Australia and New Zealand. Pilot studies are underway in Germany and France. In July 1985, a Working Group was appointed in the United Kingdom to consider policy on breast screening. The outcome was the Forrest Report (1986). As a result a nationwide mammography screening program has been introduced in the United Kingdom recruiting asymptomatic women between the ages of 50 - 64 years at 3 year intervals. The Netherlands, Finland and Sweden have also instituted policies and national programs similar to those proposed by the Forrest Committee.

In the USA, a broad group of medical organizations including the American Cancer Society, the American College of Radiology, the American Medical Association, the College of American Pathologists and the National Cancer Institute have endorsed mammography screening guidelines for women 40 years and older. While the American College of Physicians, the International Union Against Cancer and the US Preventive Services Task Force agree with these guidelines for women aged 50 and older, they do not recommend routine mammography screening of women younger than age 50.

However, recent investigations have cast doubt upon the extent that mammography screening leads to reduced mortality. The 1991 Norwegian Consensus Conference on Mammography considered whether mammography screening had

sufficient documented effect to be put into use as a nationwide service. In arriving at a decision, recent research findings and experiences with screening programs, together with the resource situation in the health system were considered. It was concluded that at this time mammography screening was not justified, considering the cost and lack of sufficient proof that mass investigation with mammography leads to prolonged survival and/or increased cure rates.

In April 1991, the Directors of Breast Screening Programs from the United Kingdom, the Netherlands, Sweden and Canada met for the Second International Cambridge Conference on Breast Cancer Screening. It was decided that a meta analysis (a statistical analysis of the combined results of different studies) of the major mammography screening studies will be undertaken. The purpose will be to determine the possible benefit of mammography screening for women before the age of 50 years.

It would appear, that despite earlier optimism about the benefits of mammography screening, a more conservative approach to breast cancer screening is being considered, both nationally and internationally, pending clear evidence of benefit of mass mammography screening.

THE MAMMOGRAPHY SCREENING DILEMMA

Over the past decade mammography screening for breast cancer has received considerable attention from researchers, health care providers and various jurisdictions of government. Early optimism regarding the benefits of mammography has resulted in the funding of a number of trials and studies and the establishment of several population screening programs (as previously described). Although much valuable data has been generated from these sources the question of whether or not to implement a mammography screening program remains a difficult one to answer definitively. A number of factors must be taken into account when considering the 'screening dilemma'. The most salient of these are:

1. the strength of the research evidence regarding the effectiveness of mammography screening for reducing mortality.

2. the cost benefit of implementing a province wide mammography screening program.

3. the apparent increasing incidence and unchanging mortality rates from breast cancer.

and

4. the increasing demands for, and utilization of, mammography for screening purposes.

Six major international studies (previously discussed) have attempted to establish if periodic screening for breast cancer with mammography in asymptomatic women will reduce mortality. The available results of these studies have been determined to be incomplete with methodological variations and problems. Overall the evidence suggests a 30% breast cancer mortality reduction from mammography screening that occurs only in the 50 - 69 age group. The data also indicate that there is a potential for large numbers of false positive and fewer but more dangerous false negatives. Mammography screening programs have begun in Western Europe, the United States and Canada. Many years will have to elapse before the extent of benefit is established. Two fundamental questions remain to be answered conclusively: should we screen at all? and if so which women should be screened?

The ongoing operation of a province wide mammography screening program involves considerable financial commitment. Additional equipment, skilled technicians, radiologists, operation of a recall registry, medical follow-up and a resulting increase in diagnostic services would easily incur expenditures of over 2.5 million dollars per year.

The high life time risk (in Canada 1 in 10 women) and the resulting death rate indicate an urgent need to prevent and better manage breast cancer in women. Priorization of fiscal resources for breast cancer research must take into

account the urgency to find both preventive measures and improved treatment.

The demand for mammography screening has been increasing steadily since 1980. The increased demand has occurred in all age groups, including women aged 40 - 49 years, despite the fact that research to date fails to indicate any mortality reduction and may in fact suggest increased risk attributable to screening women in this age group. The Malmo Study, the Swedish Two County Trial and preliminary results from the Canadian National Breast Screening Study suggest an initial increased mortality risk in asymptomatic women 40 - 49 years who undergo mammography screening.

A factor in the increased demand for mammography is that women have been influenced by mass media campaigns which have raised their awareness of breast cancer and have strongly promoted breast cancer screening with mammography. While media messages have served a useful purpose in raising awareness about breast cancer, the information provided has been incomplete, and emotionally charged, appealing to women's fear of cancer. There is variable access to information on breast health, breast cancer and the limitations and risks versus the benefits of mammographic screening.

Newspapers, magazine articles and television advertisements encourage women to "protect" themselves from breast cancer by having regular mammograms starting at age

35. Contact with these messages make it very likely that women will request and receive a referral for mammography from their physician. Health care providers are also influenced by the same media messages which strongly promote mammography.

There is consensus that as a diagnostic procedure (for women who have symptoms such as palpable "lumps") or for women with risk factors, diagnostic mammography plays a valuable role. However, currently a substantial proportion of mammograms are performed on healthy women with no abnormalities or risk factors and the numbers are steadily rising.

The dilemma, at this time, is to reduce inappropriate screening mammography and take positive action to address the high incidence of breast cancer while allowing for continued monitoring and evaluation of new and emerging research results on breast cancer and breast cancer detection.

CONCLUSIONS & RECOMMENDATIONS

A number of conclusions formed the basis on which the major recommendations were developed. These are outlined below:

CONCLUSIONS

1. The benefits of population screening with mammography are still being determined. Although studies have shown a reduction in breast cancer mortality in women 50 - 69 years, the re-evaluation of this evidence and preliminary results from the Canadian National Breast Screening Study question the extent of this benefit.

2. Emerging data in women under 50 years of age, fails to demonstrate benefit of screening mammography. Recent data suggest a trend to higher mortality in women under 50 years who have been screened.

3. A decision to implement mass population mammography screening is premature. Before any program regarding breast cancer mammography screening is undertaken by the Province of Manitoba there should be sufficient time to allow for ongoing examination of new and emerging evidence in this area, including publications of the Canadian National Breast Screening Study. The findings of the Canadian National Breast Screening

Study regarding the relative effectiveness of mammography versus professional breast examination will have major implications for the structuring of a provincial screening program.

4. Some promotional media campaigns which encourage mammography screening provide women with an unbalanced view of the benefits of mammography. In particular, women under the age of 50 are encouraged to have regular screening mammograms in spite of evidence which fails to demonstrate a benefit.

5. Expenditures on mammography for healthy women 40 - 49 years of age should be reallocated to areas such as education and research in the realm of breast cancer.

RECOMMENDATIONS

1. **That no mammography screening program be initiated in the province at this time.**

Rationale

For a screening program to be justifiable it must bring benefit to the individual while producing minimal physical and psychological harm. In the case of mammography screening for breast cancer, re-evaluation of the international studies and new evidence from the Canadian

National Breast Screening Study have cast doubt upon the extent of benefits of mammography screening in reducing breast cancer mortality and prolonging life.

In this economic climate of restraint, it is difficult to defend the diversion of resources that would be required to implement a mammography screening program when there is question of health gain. In waiting to observe the experiences of mammography screening programs currently underway, important information will be gained about outcomes, implementation and about avoiding programs that may potentially put women at risk.

Economic Implications

In the absence of a public education program, expenditures on mammography services will continue to escalate to meet demand. In 1989, 20,409 mammograms were performed in Manitoba on women aged 40 years and above at a cost of 1.6 million dollars. If the trend of increased demand and use of resources by asymptomatic women continues, costs will escalate to approximately 3 million dollars by 1992.

A comprehensive public education program directed at increasing awareness and reducing inappropriate mammography in asymptomatic women will decrease the demand for this service and contain costs.

2. That screening mammography be discouraged in asymptomatic women under the age of 50 years.

Rationale

Research literature indicates that mammography screening provides no benefit in terms of mortality reduction from breast cancer for women under 50 years of age. Furthermore, preliminary results, not statistically significant, from the Canadian National Breast Screening Study suggest more deaths in women 40 - 49 years randomized to mammography.

In some jurisdictions, the vigorous promotion of mammography screening for breast cancer detection has created a demand for this service. In Manitoba, 37% of mammograms performed in 1989 were on women in the 40 - 49 age group.

Economic Implications

In 1989, 7,548 bilateral mammograms were performed on women 40 to 49 years of age. It is estimated that 60% of these mammograms were done on asymptomatic women. If this estimate is accurate, 4,442 asymptomatic women in the 40 - 49 age group had mammograms at a cost of $350,000.

An effective public education program will reduce overall costs due to inappropriate use of mammography among women 40 - 49 years.

3. **That the provincial government support the development and implementation of an information program for health professionals. This program will be developed in collaboration with relevant professional groups and associations.**

Rationale

Studies show that women are strongly influenced by their physician's recommendations regarding breast screening. Sound policy for mammography screening requires the understanding and cooperation of an informed health care community.

Implementation Strategies of a Health Professional Education Program

A detailed information package for practicing physicians and other health professionals will be developed and distributed outlining the position and rationale adopted by the province on mammography screening, and will include an explanatory letter and relevant research articles for reference. Articles prepared for professional newsletters will increase awareness of the ongoing mammography debate.

Members of the Working Group will be available to provide continuing education/inservice information sessions to both women's groups and health agencies and to various health professional groups.

Economic Implications

The most substantive costs of the education program for health professionals will be the information package outlining the provincial position, rationale and relevant research articles on mammography screening. The development, printing and distribution of this package has been estimated at $10,000 to $15,000.

4. That a system be developed to provide women throughout the province with current information about breast cancer screening. An initial and interim measure will be the development and distribution of an information resource which focuses on the current knowledge and assists women in decision-making about mammography in conjunction with their health care provider.

Rationale

The scientific evidence to date has provided insufficient proof of overall health benefit to implement a provincial mammography screening program at this time. This recommended policy is at variance with media advertising which strongly promotes breast cancer screening with mammography. Women exposed to these promotional messages are requesting and receiving mammograms which may not be in their best interest.

A government policy not to implement a mammography screening program at this time could be perceived by the consumer as a cost saving gesture rather than one based on health concerns. A public education resource, along with education directed at health professionals is required to increase awareness of the current evidence about mammography screening and support the recommendations of this report.

A comprehensive public education campaign which includes media and interactive community education should be undertaken in the future as new research evidence further clarifies the risks, benefits and limitations of early detection of breast cancer with mammography, professional physical examination and breast self examination.

Implementation Strategies of a Public Education Program

A print resource in the form of a fact sheet will be developed by the Women's Health Directorate in consultation with the Working Group, the Canadian Cancer Society, women's groups and other relevant organizations. Distribution of this resource will be via community health offices, physician's offices, community clinics, hospitals, women's groups, resource centres and agencies, and occupational health networks. Health agencies and services will be asked to stock and display this resource prominently so they are readily available to women. Health care providers will be encouraged to use them as an adjunct to individual health counselling.

The resource would be stocked and distributed, free of charge, through the Provincial Health Information Resource Centre.

5. That the Government of Manitoba promote appropriate research in the realm of breast cancer including breast cancer screening.

Rationale

Many questions bearing on breast cancer and breast cancer screening still remain to be answered. In Manitoba, the Department of Community Health Sciences, the World Health Organization Collaborating Centre for Quality of Life in Cancer, the St. Boniface Hospital Research Centre and the Manitoba Cancer Treatment and Research Foundation are all involved in ongoing research in the early detection and treatment of breast cancer.

The following areas were identified for further research:

- To establish an integrated registry, in consultation with Manitoba Health Services Commission and the Manitoba Cancer Treatment and Research Foundation, for

breast cancer in Manitoba to document present clinical and radiology activity (which is a mixture of clinical and screening mammography). As a component of a research project this registry would provide a data base to further guide eventual decisions about mammography screening in Manitoba.

- Manitoba women participated in the Canadian National Breast Screening Study. In collaboration with Manitoba Health, explore the feasibility of linking Manitoba Health Services Commission data with the datafile of the Canadian National Breast Screening Study in order to conduct a retrospective study to ascertain the utilization of health care resources by Manitoba women who participated in the Canadian National Breast Screening Study.

- To enable retrospective correlation analysis between pathology findings, breast cancer treatment and mortality. This will require the establishment of a breast biopsy registry and storage unit to collect additional pathologic information from biopsy materials.

6. **That a Breast Cancer Screening Advisory Group be established, with appropriate membership, to monitor evidence regarding breast cancer screening including the Canadian National Breast Screening Study results. Reassessment of recommendations and economic implications on a breast cancer screening program for Manitoba women should be ongoing.**

Rationale

As outlined in the body of this report, it is anticipated that the Canadian National Breast Screening Study, the meta Analysis of the Cambridge Conference on Breast Cancer Screening and the review of the Canadian Co-ordinating Office for Health Technology Assessment will be able to provide new information about breast cancer screening and the pending results will have an influence on screening policy. The Committee's view is that it is imperative that the decision to implement a costly breast cancer screening program be delayed until detailed results become available for review.

In awaiting the results of the Canadian National Breast Screening Study, the Manitoba Government should continue to support Manitoba's participation in ongoing cross jurisdictional meeting, to collaborate and facilitate the exchange of information between provinces about breast cancer and screening programs.

CONCLUDING SUMMARY

On the basis of currently available scientific evidence, expert opinion, and much deliberation, the Working Group concludes that committing large amounts of money to a large scale provincial mammography screening program is not advisable at this time. Re-examination of earlier studies and information from existing programs has resulted in growing controversy which has reduced earlier optimism regarding the health benefits of mammography screening.

We urge dissemination of information to women and health professionals, and further research in the realm of breast cancer until convincing evidence of breast cancer mortality reduction is provided that justifies a breast cancer screening program.

In the interim we recommend the establishment of a Breast Cancer Screening Advisory Group to monitor evidence on breast cancer screening and if necessary, based on the newer evidence, reassess the advisability of a breast cancer screening program for Manitoba women.

BIBLIOGRAPHY

1. Baines, C. J., Miller, A.B., Wall, C. et al. (1986) **Sensitivity and specificity of first screen mammography in the Canadian National Breast Screening Study. A preliminary report of 5 centers.** Radiology. 160 : 295-298.

2. Council on Scientific Affairs (1989) **Mammographic screening in asymptomatic women aged 40 years and older.** Journal of the American Medical Association. 261 (17) : 2535-2542.

3. Cribb, A. and Haran, D. (1991) **The benefits and ethics of screening for breast cancer.** Public Health 105 : 63-67.

4. Eddy, David M., and McGivney, William (1988) **The value of mammography screening in women under age 50 years.** Journal of the American Medical Association. 259 (10) : 1512-1519.

5. Feig, Stephen A. (1988) **Decreased breast cancer mortality through mammographic screening results of clinical trials.** Radiology. 167 : 659-665.

6. Greenberg, E. R., Stevens, M. (1986) **Recent trends in breast surgery in the United States and the United Kingdom** British Medical Journal. 292 : 1487-1491.

7. Miller, Anthony (1991) **Is routine mammography screening appropriate for women 40-49 years of age?** American Journal of Preventive Medicine. 7 (1) :55 - 61.

8. Miller, A. B., Chamberlain, J., Day, N.E., Hakama, M. and Prorok, P.C. (1990) **Report on the workshop of the UICC project on evaluation of screening for cancer.** International Journal of Cancer. 46 : 761 - 769.

9. Moskowitz, M. (1987) **Cost of screening for breast cancer.** Radiologic Clinics of North America. 25 (5): 1031 - 1037.

10. Quebec. Conseil d'evaluation des technologies de la sante du Quebec. 1990. **Screening for breast cancer in Quebec: Estimates of health effects and of costs** Montreal: Ministre de la Sante et des Services sociaux du Quebec. Conseil d'evaluation des technologies de la sante du Quebec.

11. Rutqvist, Lars E., Miller, Anthony B., Andersson, Ingvar, Hakama, Matti, Hakulinen, Tomo, Sigfusson, Baldur F., and Tabar, Laszlo. (1990) **Reduced breast cancer mortality with mammography screening - An assessment of currently available data.** International Journal of Cancer. Supplement 5 : 76-84.

12. Schmidt, Johannes, G. (1990). **The epidemiology of mass breast cancer screening - A plea for a valid measure of benefit.** Journal of Clinical Epidemiology. 43 (3) : 215-225.

13. Shapiro, Sam (1990). **A dissent from Dr. Schmidt's appraisal of evidence on breast cancer screening.** Journal of Clinical Epidemiology. 413 (3) : 227-234.

14. Skrabnek, Petr (1989) **Mass mammography: The time for reappraisal.** International Journal of Technology Assessment in Health Care. 5 : 423-430.

15. Skrabnek, Petr (1985) **False premises and false promises of breast cancer screening.** The Lancet, August 10 : 316-319

16. Technology Assessment Reports. **Norwegian consensus conference on mammography.** International Journal of Technology Assessment in Health Care.

17. The Workshop Group.(1989) **Reducing deaths from breast cancer in Canada.** Canadian Medical Association Journal. 141 : 199-201.

18. U. S. Preventive Service Task Force. (1989) **Guide to clinical preventive services: an assessment of the effectiveness of 169 interventions.** Baltimore, Williams & Wilkins.

19. Wilson, J.M.G. and Jungner, G. **Principles and practice of screening for disease.** (Public Health Paper No. 34). World Health Organization, Geneva, 1968.

20. Woolmark, N. (1985) **Minimal breast cancer: Advance or anachronism.** Canadian Journal of Surgery. 28: 252 -255

21. Working Group. **Breast cancer screening report to the Health Ministers of England, Wales, Scotland and Northern Ireland.** London, HM Stationery Office, 1987.

22. Wright, Charles J. (1986) **Breast cancer screening: A different look at the evidence.** Surgery. 100(4): 594 - 598.